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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,199	01/04/2002	Gregory Newton Brewer	P 284145	2505
23117	7590	03/16/2004	EXAMINER	
NIXON & VANDERHYE, PC			PATEL, MITAL B	
1100 N GLEBE ROAD			ART UNIT	PAPER NUMBER
8TH FLOOR			3743	
ARLINGTON, VA 22201-4714			DATE MAILED: 03/16/2004	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/035,199	BREWER ET AL.
	Examiner	Art Unit
	Mital B. Patel	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 January 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 27-69 is/are pending in the application.  
 4a) Of the above claim(s) 28-56 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 27 and 57-69 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. 09/469954.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment/Arguments***

1. Applicant's arguments filed 1/8/04 have been fully considered but they are not persuasive.
2. In response to Applicant's arguments that Lundberg does not teach a mask-fit test pressure but rather teaches measuring leakage, it should be noted that leakage is correlated to and indirectly related to the fit of the mask. Furthermore, Lundberg teaches testing or checking the operation of the breathing equipment, and Lundberg defines a breathing mask to be a part of the breathing equipment. For further clarity on the mask-fit test pressure please also refer to Col. 5, lines 33-63 which makes a more specific reference to fitting of the mask to the user's face along with comparative data with respect to measuring the pressure inside and outside of the mask against a predetermined pressure value.
3. Please also note that the Examiner maintains the finality of the restriction requirement that was set forth in the previous office action.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 27 and 57-62, 64, 65, 66, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Lundberg (US 5860418).

6. **As to claim 27**, Lundberg teaches a method for determining a mask-fit test pressure to be applied to a wearer's mask by ventilatory assistance apparatus, wherein the mask-fit pressure is adaptively determined from prior use (**See Col. 3, lines 16-25 and Col. 4, lines 28-52**).

7. **As to claim 57**, Lundberg teaches a method wherein the mask-fit pressure is determined based on a prior use by comparing leak flow to a threshold leak flow value (**See Col. 3, lines 16-25 and Col. 4, lines 28-52; also Col. 4, lines 53-61**).

8. **As to claim 58**, Lundberg teaches a method wherein the leak flow is determined over a predetermined time period (**See Col. 4, lines 28-52; also Col. 4, lines 53-61**).

9. **As to claim 59**, Lundberg teaches a method wherein the leak flow is determined based on a time constant of about 10 seconds (**See Col. 4, lines 28-52; also Col. 4, lines 53-61**).

10. **As to claim 60**, Lundberg teaches a method wherein the method is practiced with a CPAP device having two functional modes (**See Col. 2, lines 38-67**).

11. **As to claim 61**, Lundberg teaches a method wherein determining the mask-fit pressure includes sampling pressure signals in a gas supply assembly associated with the mask (**See Col. 3, lines 64-67, Col. 4, lines 1-27**).

12. **As to claim 62**, Lundberg teaches a method wherein sampling pressure signals occurs in a delivery tube (**See Col. 4, lines 44-52**) of the gas supply assembly.

13. **As to claim 64**, Lundberg teaches a method wherein sampling pressure signals occurs at predetermined intervals (**See Col. 3, lines 64-67, Col. 4, lines 1-27**).

14. **As to claim 65**, Lundberg teaches a method wherein the sampling occurs at about 20 millisecond intervals (**See Col. 4, lines 28-42**).

15. **As to claim 66**, Lundberg teaches a method wherein sampling pressure signals includes determining a flow of gas in the mask and generating a delivery pressure signal (**See Col. 4, lines 28-52; also Col. 4, lines 53-61**).

16. **As to claim 69**, Lundberg teaches a method further comprising varying at least one setting relating to test pressure intervals, test pressure period, and determined test pressure.

#### *Claim Rejections - 35 USC § 103*

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 63, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg in view of Rapoport et al (US 5535739).

19. **As to claim 63**, Lundberg teaches essentially all of the limitations except for wherein the sampling pressure signals occurs in a blower of the gas supply assembly. However, Rapoport does teach the use of a blower-motor as a means of providing gas to the patient. Furthermore, the use of a blower-motor allows for the speed to be

controlled at which the gas is supplied. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the gas delivery device of Lundberg with that taught by Rapoport since they are mechanical expedients and the function of the gas delivery device is not altered with respect to delivering a gas to a patient and because the blower-motor allows for variation in the speed at which the gas is delivered.

20. **As to claim 67**, Lundberg teaches a method wherein determining the mask-fit pressure also includes processing the sampled pressure signals and producing a control signal based on the processed signals, wherein the control signal is provided to a motor to provide a determined treatment pressure (**See Col. 5, lines 64-67 and Col. 6, lines 1-13**).

21. **As to claim 68**, Lundberg teaches a method further comprising comparing a signal representative of actual delivery pressure with the control signal (**See Col. 5, lines 64-67 and Col. 6, lines 1-13**).

### **Conclusion**

22. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

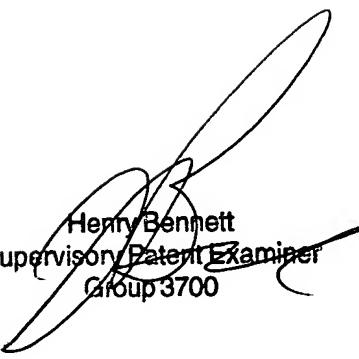
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mbp

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